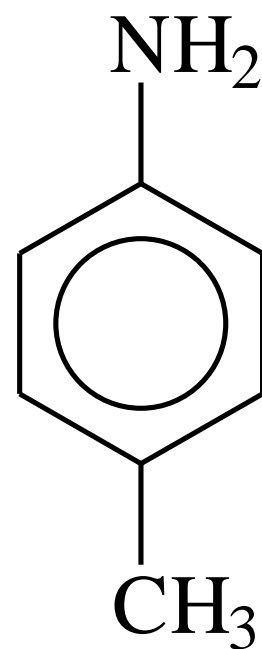


# *p*-Toluidine



Molecular Weight: 107.15

CAS Registry No.: 106-49-0

# Listing History: *p*-Toluidine

- Listed under Proposition 65 on January 1, 1990
- Originally classified by U.S. EPA as a Group B2 carcinogen (U.S. EPA, 1986)
- Subsequently reclassified as a Group C carcinogen (U.S. EPA, 1988)

# Reviews by Other Authoritative Bodies

## ■ NIOSH

- ◆ 1992 *Recommendations for Occupational Safety and Health, Compendium of Policy Documents and Statements*
- ◆ “potential for cancer; tumors of the liver in animals”
- ◆ “should be designated” as a potential occupational carcinogen

# Reviews by Other Authoritative Bodies (cont.)

- U.S. FDA (1998, 1999)
  - ◆ Impurity in dye (D&C Violet No. 2) used in surgical sutures and tacks
  - ◆ “carcinogenic impurity that may be present”
  - ◆ “*p*-toluidine is a carcinogen in the mouse”

# Carcinogenicity Data Available: *p*-Toluidine

- Mouse long-term diet studies  
(Weisburger *et al.*, 1978)
  - ◆ Increased hepatomas in male and female mice
  
- Male rat long-term diet study  
(Weisburger *et al.*, 1978)
  - ◆ No increased tumor incidence

# Liver Tumors in CD-1 Mice (Weisburger, 1978)

Tumor Site and Type		Dose Groups		
		Control	Low-dose	High-dose
<i>Males</i>		3/18 (simult.)		
Liver	hepatoma	7/99 (pooled)	8/17 <sup>*</sup>	9/18 <sup>**</sup>
<i>Females</i>		0/20 (simult.)		
Liver	hepatoma	1/102 (pooled)	2/21	3/17 <sup>***</sup>

\* p = 0.0014 (vs. pooled controls)

\*\* p = 0.038 (vs. simult. controls)

\*\*\* p = 0.009 (vs. pooled controls)

## Other Relevant Data: *p*-Toluidine

- Non-positive mutagenicity assays in *Salmonella* and *E. coli*
- Increased unscheduled DNA synthesis in rat hepatocytes (Thompson *et al.*, 1983)
- Decreased testicular DNA synthesis in mice following oral treatment (Seiler *et al.*, 1977)
- Hepatic DNA binding in rats (Brock *et al.*, 1990)

# Summary: *p*-Toluidine

- NIOSH and U.S. FDA have designated *p*-toluidine as a carcinogen
- Scientific evidence supporting the designation was positive bioassays in male and female mice
- Other relevant data include positive DNA synthesis and hepatic DNA binding assays